# C-22 Autoclave Monitoring

## I. Purpose

Successful sterilization of any item depends not only on proper cleaning but also on proper preparation, packaging, and positioning in the load. These elements are as critical as choosing the correct exposure time and temperature. It is important that each item be prepared in a manner that will facilitate air removal, steam penetration, and steam contact with all surfaces of the device that are intended to be sterilized. In addition, efficient steam removal is necessary for proper drying and the prevention of wet packages at the end of the sterilization cycle

## II. Background

The use of autoclave sterilization has been an indispensable method of assuring that today's equipment is sterile and safe, but what assurance do you have that your autoclave is functioning properly? The Centers for Disease Control (CDC) vol. 42/No. RR-9 - "Proper functioning of sterilization cycles should be verified by the periodic use (at least weekly) of biological indicators (i.e. spore tests)."

## III. Policy

The policy applies to all OTS Contractor and Government employees who work at NCI-Frederick and off-site facilities. EHS provides laboratory personnel semi-annual autoclave monitoring services to determine efficiency and adequacy of microbiological kill.

## IV. Definitions

B. stearothermophilus**:** A biological indicator broadly defined as a characterized preparation of a specific microorganism that provides a defined and stable resistance to a specific sterilization process.

Incubator: a device used to grow and maintain microbiological cultures or cell cultures.

Sterilization: the complete elimination or destruction of all living organisms.

## V. Responsibilities

Environment, Health and Safety Directorate (EHS):

1. EHS will send a B. stearothermophilus ampoule to a designated contact person for each autoclave to be tested semi-annually for monitoring/validation purposes.

2. The identified contact is sent an ampoule for each autoclave for which they are responsible. Instructions are provided for the placement of an ampoule within the autoclave during the run. The contact is to return the ampoule to Biological Safety for incubation to determine if the autoclave has provided a proper microbiological kill. Results are maintained within EHS. Contacts will be notified if results are not satisfactory. Autoclave owners are encouraged to institute a routine monitoring program independently which includes keeping a log and utilizing biological indicators on a regular basis. For more information on developing an autoclave-monitoring program contact EHS at 301-846-1451.

OTS Contractor and Government Investigators

1. Assure that all autoclaves in their department are being tested;
2. Provides EHS with contact information;

## VI. Procedure

1. Identify all contacts from the Autoclave database. This is a voluntary program.
2. On the month when autoclave should be tested, send out memo to contact person. Instructions should be included for procedure to be followed using Attest ampoules. Contact person should send ampoules back to EHS in a 50ml conicle tube or plastic baggie.
3. Upon receiving ampoule from contact person, place ampoule in 56° C incubator using manufacturer's recommendations for breaking inner tube within ampule.


4. Include a control ampule in incubator.
5. Incubate for 24 hours.
6. Result interpretations:
   Test ampoule: Purple
   Control: Yellow
   (purple) indicates the B. stearothermophilus was killed during autoclave run and is a successful test..
7. Maintain records to include results (P/F), date, contact person, autoclave information.
8. If test ampoule fails (turns yellow), conduct a retest.
9. If the test ampoule fails a second time, notify the autoclave user of the results, and the contact person will put in a work order to have the autoclave checked (x1068).
10. Once autoclave has been checked by FME, conduct a final test.

## VII. Records Retention and Disposal

The following records regarding autoclave use must be kept:

1. On-site maintenance records.
2. Autoclave use log. Each load of material inactivated shall be logged as follows:
    i. Date, time and operators name.
    ii. Type of waste
    iii. Confirmation of sterilization
    iv. Record the temperature, pressure and length of time the load is sterilized.
    v. Autoclave printout is saved if the autoclave unit has a working printer.

## VIII. References

1. Centers for Disease Control and Prevention (CDC)
Guidelines for Infection Control in Dental Health-Care Settings --- 2003
MMWR December 19, 2003 / 52(RR17); 1-61. ).
2. Autoclave Quality Control Policy, Northwestern University - http://www.research.northwestern.edu/ors/forms/bio-gen-autoclave-qc-policy-101110.pdf
3. Sterilization Monitoring – CDC - http://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm